

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

LAW ENFORCEMENT HEALTH
BENEFITS INC., on behalf of itself and all
others similarly situated,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION; NOVARTIS AG;
NOVARTIS CORPORATION; PAR
PHARMACEUTICAL, INC.; ENDO
PHARMACEUTICALS, INC.; and ENDO
INTERNATIONAL PLC,

Defendants.

Civil Action No. 1:18-05603

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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Plaintiff Law Enforcement Health Benefits Inc. (“LEHB” or “Plaintiff”) brings this class action, on behalf of itself and all others similarly situated, for violations of state antitrust, consumer protection, and common laws to recover damages caused by Novartis Pharmaceuticals Corporation, Novartis AG, and Novartis Corporation (collectively, “Novartis”); Par Pharmaceutical, Inc. (“Par”); and Endo Pharmaceuticals, Inc. and Endo International plc (collectively, “Endo” and together with Novartis and Par, “Defendants”).

1. As detailed below, Defendants entered into a pay-for-delay agreement whereby (1) Par agreed not to compete in the market for Exforge® from at least September 21, 2012 until September 30, 2014, thereby allocating the entire Exforge® market to Novartis until that date; and (2) Novartis agreed not to compete in the generic Exforge® market from September 30, 2014 to March 30, 2015 thereby allocating the entire market for generic versions of Exforge® to Par for that six-month period. The purpose and effect of the agreement between Defendants was: (a) to delay generic entry of Exforge® in order to lengthen the period in which Novartis’ brand Exforge® could monopolize the market and make supra-competitive profits; (b) to keep an authorized generic off the market during Par’s 180-day generic exclusivity period, thereby allowing Par to monopolize the generic market for Exforge® during that period, and allowing Par to make supra-competitive profits; (c) to prevent any potential patent litigation relating to Exforge® and its generic equivalents; and (d) to raise and maintain the prices that LEHB and other members of the Class would pay for Exforge® at supra-competitive levels until the effects of Defendants’ anticompetitive conduct ceased. Defendants’ scheme allowed them to make hundreds of millions of dollars from the supra-competitive pricing of Exforge®.

2. Absent this unlawful and anticompetitive agreement, LEHB and members of the class it seeks to represent in this complaint would have benefited from competition for generic

versions of Exforge® earlier than they did, and would have been able to purchase Exforge® at significantly lower prices, rather than being forced to pay supra-competitive prices for branded Exforge®. LEHB seeks to represent a class of all indirect purchasers of Exforge® or its generic equivalent from September 21, 2012 until the effects of Defendants' conduct ceased. Plaintiff's allegations are based on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

I. INTRODUCTION

3. *Novartis develops Exforge®.* In 2007, Novartis developed a combination drug to lower high blood pressure. Specifically, Novartis created Exforge®, the first high blood pressure medication to combine the calcium channel blocker ("CCB") amlodipine besylate with the angiotensin-II receptor blocker ("ARB") valsartan. Novartis claimed that Exforge® offered patients the convenience of a reduced pill load for their hypertension medication that would increase patient adherence. On June 20, 2007, the FDA approved Novartis' New Drug Application ("NDA") for Exforge® tablets.

4. *Par and Synthon were the first generic filers.* In 2007, Par and Synthon Pharmaceuticals Inc. ("Synthon") became the first generic manufacturers to seek FDA approval to launch generic Exforge®. On October 1, 2007, Par was the first to file an Abbreviated New Drug Application ("ANDA") for the 10/160, 5/160 and 10/320 milligram strengths of amlodipine and valsartan, respectively, while on November 26, 2007, Synthon was the first to file an ANDA for the 5/320 milligram strength. In their filings, Par and Synthon each asserted that (1) they would not seek final FDA approval until the September 21, 2012 expiration of exclusivities associated with U.S. Patent No. 5,399,578 ("the '578 Patent"); but (2) they would seek final FDA approval to market, and intended to launch, their ANDA products prior to the expiration of the follow-on patents, U.S. Patent Nos. 6,294,197 ("the '197 Patent") and 6,395,728 ("the '728 Patent"), which

they claimed were invalid and/or would not be infringed by Par's and Synthon's proposed generic equivalents. As the first filers, Par and Synthon earned the right to keep other generic companies off the market for 180 days. Significantly, though, neither Par nor Synthon could prevent Novartis from selling or licensing its own generic (referred to as an "authorized generic" or "AG"). Brand companies frequently launch or license authorized generics, particularly during a first generic filer's 180-day exclusivity period, in an effort to prevent the massive loss of revenue a brand suffers when generics enter the market. The brand's authorized generic typically takes up to 50% of generic sales away from the first generic filer. In effect, an authorized generic permits the brand to recapture some of the sales that it otherwise would lose to the first generic filer. The FDA approved Par and Synthon's ANDA applications in 2010, and Par subsequently purchased Synthon's ANDA.¹

5. ***Par and Synthon earn 180 days of generic exclusivity.*** As the first filers, Par and Synthon earned the right to keep other generic companies off the market for 180 days. Significantly, though, neither Par nor Synthon could prevent Novartis from selling or licensing its own generic (referred to as an "authorized generic" or "AG"). In effect, an authorized generic permits the brand to recapture some of the sales that it otherwise would lose to the first generic filer.

6. ***Novartis does not sue to enforce its patents.*** Despite receiving notice that Par and Synthon intended to manufacture generic Exforge® before the '197 Patent and '728 Patent expired, Novartis did not file a lawsuit against Par or Synthon for infringement of those patents

¹ On November 30, 2011, Par entered into an asset purchase agreement with Synthon under which Par would acquire Synthon's ANDA for a generic version of Exforge® (5 mg/320 mg and 10 mg/320 mg of amlodipine and valsartan, respectively). On December 30, 2011, Par closed on this asset purchase agreement. By acquiring Synthon's ANDA for generic Exforge®, Par would be the only generic first filing manufacturer of Exforge®.

within the 45-day time period set forth in the statute that triggers an automatic 30-month stay of ANDA approval. Upon information and belief, Novartis did not initiate such litigation because it believed such patents were weak and/or likely be found invalid.

7. ***Unlawful pay-for-delay agreement.*** Rather than compete with new generic drugs on the market or sue to protect its patent rights, Novartis entered into an agreement with Par to delay entry of generic Exforge® to the market. As part of the anticompetitive agreement, Novartis agreed to pay Par to stay out of the Exforge® market for over two year and agreed not to launch its own authorized generic version of Exforge®. Novartis' no-authorized-generic ("no-AG") promise was worth hundreds of millions of dollars in additional sales to Par during its 180-day exclusivity period; sales that would have gone to Novartis had it launched an authorized generic.

8. ***Delay of generic entry.*** In the absence of this pay-for-delay agreement, Novartis and Par each would have launched a generic version of Exforge® as early as September 21, 2012 (the day the '578 Patent expired), and, in any event, well before September 30, 2014, the date before which Par agreed not to enter the market. Additional generics would have launched six months later, after Par's 180-day exclusivity period expired. The availability of these additional generics to the market would have continued to drive prices down to the benefit of all drug purchasers.

9. ***Injury to the class.*** As a result of Defendants' unlawful pay-for-delay agreement, drug purchasers likely paid hundreds of millions of dollars in overcharges as Novartis continued to sell Exforge® at supra-competitive prices without competition for an additional two years past September 2012. In the absence of this unlawful agreement, Par would have entered the market earlier than September 2014, ending Novartis' monopoly and bringing competition and lower prices to consumers of fixed combination products comprising amlodipine and valsartan, as well

as to third party payors who reimburse all or part of the purchase price of Exforge® and its generic equivalents. To redress the injury to the market for fixed combination products comprising amlodipine and valsartan market, Plaintiff brings this action on behalf of a state law damages class consisting of class members who purchased or reimbursed part or all of the purchase price of Exforge® or its AB-rated generic equivalents.

II. PARTIES

10. Plaintiff LEHB is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code to provide health benefits to its eligible participants and beneficiaries. LEHB's members are current and retired sworn Philadelphia Police Officers, Deputy Sheriffs, and County Detectives, and their dependents. LEHB was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical and hospital care or benefits, including dental, optical and prescription drug benefits, to approximately 23,000 beneficiaries and covered spouses and dependents. LEHB maintains its principal place of business in Philadelphia, Pennsylvania. During the Class Period (hereinafter defined), LEHB purchased and/or provided reimbursement for some or all of the purchase price for Exforge® and/or its generic equivalents, other than for resale, at supra-competitive prices. LEHB paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets and customers. Given its plan members' past purchases of Exforge® and generic Exforge®, LEHB anticipates that it will continue to purchase and/or provide reimbursement for Exforge® and generic Exforge® in the future, and thus has been and will continue to be injured by Defendants' conduct.

11. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware. Novartis Pharmaceuticals Corporation's principal place of business is at One Health Plaza, East Hanover, New Jersey, 07936. Novartis Pharmaceuticals

Corporation is a subsidiary of Defendant Novartis AG and the NDA holder/applicant as well as a distributor for the prescription drug Exforge®. Novartis Pharmaceuticals Corporation has locations in New York, New Jersey and California. As the pharmaceuticals unit of Novartis Corporation and Novartis AG, Novartis Pharmaceuticals Corporation develops, manufactures, sells, and markets Novartis Corporation's and Novartis AG's drugs in the United States.

12. Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and a place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

13. Novartis Corporation is a corporation organized and existing under the laws of the State of New York, having its principal place of business at One Health Plaza, East Hanover, New Jersey, 07936. Novartis Corporation is essentially the U.S. headquarters of Switzerland-based Novartis AG. Novartis Corporation handles the administration, sales, and marketing of a wide variety of prescription drugs, vaccines, consumer medicines, and veterinary products, including Exforge®. It is the parent corporation of Novartis Pharmaceuticals Corporation—its and Novartis AG's pharmaceuticals unit.

14. Par Pharmaceutical, Inc. was a corporation organized and existing under the laws of the State of New York and having its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York, 10977.

15. Endo Pharmaceuticals, Inc. is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania, 19317.

16. Endo International plc is a private limited company incorporated and existing under the laws of Ireland, having its principal place of business at 1st Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, and a U.S. headquarters at 1400 Atwater Drive, Malvern, Pennsylvania, 19355. On September 28, 2015, Endo completed an acquisition of

Par Pharmaceutical, Inc. and is therefore the successor in interest to Par Pharmaceutical, Inc. Post-acquisition, Endo combined legacy Par Pharmaceutical, Inc. with its existing generics subsidiary, Qualitest Pharmaceuticals, naming the segment Par Pharmaceutical, Inc. d/b/a Par Pharmaceutical

17. Par Pharmaceutical, Inc. d/b/a Par Pharmaceutical is a corporation organized and existing under the laws of the State of New York and having its principal place of business at 6 Ram Ridge Road, Chestnut Ridge, New York, 10977.

18. Novartis, Endo, and Par are referred to in this complaint collectively as “Defendants.”

19. Defendants’ wrongful actions described below were and are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by Defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of Defendants’ affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

20. This action is instituted for damages under the antitrust, consumer protection, and common laws of various states, as described more fully in the Claims for Relief, *infra* Section XIV.

21. This Court has jurisdiction over this matter under 28 U.S.C. §§ 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds \$5,000,000, and at least one member of the class is a citizen of a state different from that of one of the defendants.

22. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

23. Pursuant to 28 U.S.C § 1391(b), (c) and (d) (general venue provisions), venue is proper in this judicial district because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the affected interstate trade and commerce described below has been carried out in this District. Further, Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

24. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. CONTINUING VIOLATIONS

25. This complaint alleges a continuing course of conduct (including conduct within any relevant limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, LEHB and the members of the Class can recover for damages that they suffered during any applicable limitations period.

V. CLASS ACTION ALLEGATIONS

26. LEHB, on behalf of itself and all other similarly situated indirect purchasers, seeks damages, measured as overcharges, trebled where available under applicable law, against Defendants based on allegations of anticompetitive conduct in the market for Exforge® and its AB-rated generic equivalents.

27. LEHB brings this action on behalf of itself and as a class action under Federal Rules of Civil Procedure 23(a) and (b)(3) seeking damages pursuant to the antitrust, unfair competition, and consumer protection laws of the states and territories listed in the Claims for Relief, *infra*, on behalf of the following class (the “Class”):

All persons and entities in the United States and its territories who indirectly purchased, paid, and/or provided reimbursement for brand Exforge® and/or its AB-rated generic equivalents during the Class Period (i.e., beginning at least as early as September 21, 2012, and ongoing until the effects of Defendants’ conduct cease).

28. The following persons or entities are excluded from the proposed Class:

- a. Defendants including any predecessor or successor of Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates;
- b. All federal and state governmental entities, except for governmental-funded employee benefit plans;
- c. All persons or entities who purchased Exforge® or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates, including any predecessor or successor of Defendants;
- d. Fully insured health plans (i.e., health plans that purchased insurance covering 100% of the plan’s reimbursement obligations to its members);
- e. Any “flat co-pay” consumers whose purchases of Exforge® or generic Exforge® were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;
- f. Pharmacy benefit managers; and
- g. The judges or justices involved in this action and any members of their immediate families.

29. Members of the Class are so numerous and so geographically dispersed that joinder of all members of the Class is impracticable. Plaintiff believes that there are thousands of members of both Class widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join

them together. Further, the Class are readily identifiable from information and records in Defendants' possession.

30. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and members of the Class were harmed by the same wrongful conduct by Defendants in that they paid artificially inflated prices for branded and generic Exforge® and were deprived of the benefits of earlier and more robust competition from cheaper generic equivalents of Exforge® as a result of Defendants' wrongful conduct.

31. Plaintiff will fairly and adequately protect and represent the interests of the members of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the other members of the Class.

32. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigations involving pharmaceutical products.

33. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual members of the Class because Defendants have acted on grounds generally applicable to the entire Class, thereby rendering overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

34. Questions of law and fact common to the Class include, but are not limited to:

- a. whether Defendants conspired to delay generic competition for Exforge®;
- b. whether Defendants' actions constituted an illegal market allocation agreement;
- c. whether Novartis' agreement with Par was necessary to yield some cognizable, non-pretextual procompetitive benefit;
- d. whether Defendants' agreement created a bottleneck to further delay generic competition for Exforge®;

- e. whether Defendants' agreement harmed competition;
- f. whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Exforge®;
- g. determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic conduct caused;
- h. whether, and if so to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to LEHB and members of the Class;
- i. whether the alleged conduct violated state laws;
- j. whether Defendants unjustly enriched themselves to the detriment of LEHB and the members of the Class, thereby entitling LEHB and the members of the Class to disgorgement of all benefits derived by Defendants;
- k. whether the conduct of Defendants, as alleged in this Complaint, caused injury to the business or property of LEHB and the members of the Class;
- l. the effect of Defendants' alleged conduct on the prices of Exforge® and generic Exforge® sold in the United States during the Class Period;
- m. the appropriate class-wide measure of damages for the Class;
- n. whether Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;
- o. to the extent such pro-justifications exist, whether there were less restrictive means of achieving them;
- p. whether direct proof of Defendants' monopoly power is available and, if so, whether it is sufficient to prove Defendants' monopoly power without the need to define the relevant market; and
- q. whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce.

35. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including

providing injured persons or entities a method for obtaining redress on claims that practicably could not be pursued individually, substantially outweigh potential difficulties in management of this class action.

36. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.

37. Plaintiff knows of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

VI. REGULATORY FRAMEWORK

A. The Regulatory Structure for Approval and Substitution of Generic Drugs.

38. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”),² manufacturers that create a new drug must obtain approval from the Food and Drug Administration (“FDA”) to sell the product by filing a NDA.³ Complete NDAs include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.⁴

39. When the FDA approves a brand manufacturer’s NDA, the manufacturer may cause the FDA to list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the “Orange Book”) certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patent(s).⁵ A brand manufacturer has 30 days in which to

² Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 *et seq.*).

³ 21 U.S.C. §§ 301-392.

⁴ 21 U.S.C. § 355(a), (b).

⁵ Patents covering processes for making drug products, for example, may not be listed in the Orange Book.

list patents issued after approval of an NDA in the Orange Book in order for the patent to be considered timely filed.⁶

40. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the authority or resources to verify the manufacturer's representations for accuracy or trustworthiness and relies completely on the manufacturer's truthfulness about the validity and applicability of any Orange Book-listed patents.

1. The Hatch-Waxman Amendments.

41. In 1984, Congress modified the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a generic manufacturer to file an ANDA with the FDA that relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA. An ANDA filer need demonstrate only that the generic drug is pharmaceutically equivalent and bioequivalent⁷ (together, "therapeutically equivalent") to the brand name drug. The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the bloodstream at a similar rate over a similar period of time are expected to be equally safe and effective. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

⁶ 21 U.S.C. § 355(b)(1), (c)(2).

⁷ Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the active ingredient of the brand counterpart. *See* 21 U.S.C. § 355(j)(8)(B).

42. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

43. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled \$21.6 billion; by 2013, total prescription drug revenues had climbed to more than \$329.2 billion, with generics accounting for 86% of prescriptions.⁸ When a generic form is available, generics are dispensed approximately 95% of the time.⁹

2. Regulatory exclusivities for new drugs.

44. To promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provided for exclusivities (or exclusive marketing rights) for new drugs. If statutory requirements are met, the FDA grants these exclusivities upon approval of a drug. These exclusivities are listed in the Orange Book as covering the brand, along with any applicable patents, and can run concurrently with the listed patents.

45. One such exclusivity, New Chemical Entity ("NCE") exclusivity, applies to products containing chemical entities never previously approved by the FDA either alone or in combination. If the FDA grants a product NCE exclusivity, the agency may not accept for review

⁸ See IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013*, 30, 51 (2014).

⁹ *Id.* at 51.

any ANDA for a drug containing the same active moiety (i.e., the part of the drug that makes it work as it does) for five years from the date of the NDA's approval, unless the ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.¹⁰

46. A drug product may also receive an additional three-year period of exclusivity if its sponsor submits a supplemental application that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that are essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved – leading to seven to eight years of exclusivity for the brand manufacturer.¹¹

47. Regulatory exclusivities are not always absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.¹²

3. ANDA paragraph IV certifications.

48. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- a. That no patent for the brand has been filed with the FDA (a "paragraph I certification");
- b. That the patent for the brand has expired (a "paragraph II certification");
- c. That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification");
or

¹⁰ 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

¹¹ 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

¹² *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

- d. That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").¹³

49. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years,¹⁴ or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions is met, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

4. The first filer's 180-day exclusivity period.

50. Generics may be classified as (i) first filer generics, (ii) later generic filers, or (iii) authorized generics.

51. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer ("first filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.¹⁵ That is, when a first filer submits a substantially complete ANDA with the FDA and

¹³ 21 U.S.C. § 355(j)(2)(A)(vii).

¹⁴ 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the significantly stronger showing required to obtain a preliminary injunction to prevent the generic's launch.

¹⁵ 21 U.S.C. § 355(j)(5)(B)(iv), (D).

certifies that the unexpired patents listed in the Orange Book are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first generic has been on the market for 180 days.¹⁶

52. The 180-day window is often referred to as the first filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer, because a brand manufacturer (such as Novartis) can launch an authorized generic ("AG") at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry to recoup some of the sales they would otherwise lose.

53. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.¹⁷

54. A first filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

B. The Competitive Effects of AB-Rated Generic Competition.

55. As noted above, generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is

¹⁶ Or, until its first filer exclusivity has been forfeited. A first filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. There is no forfeiture in the instant case.

¹⁷ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic manufacturer. This discount typically increases to 50% to 80% (or more) when multiple generic competitors compete in the sale for a given drug. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers.

56. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use facilitate both rapid price decline and rapid sales shift from brand to generic purchasing following the launch of AB-rated generic. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. The Federal Trade Commission (“FTC”) has found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.¹⁸

57. Generic competition enables all indirect purchasers of a drug (i) to purchase generic versions of the drug at substantially lower prices, and/or (ii) to purchase the brand at a reduced price.

58. Until a generic version of the brand enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can therefore continue profitably to charge supra-competitive prices. Brand manufacturers, such as Novartis, are well aware of generics’ rapid erosion of their brand sales. Brand manufacturers thus

¹⁸ See FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumersbillions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> (“FTC Pay-for-Delay Study”).

seek to extend their monopolies for as long as possible, sometimes resorting to illegal means to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

59. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.¹⁹ Because of state substitution laws, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

60. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market, though the brand's AG can be, and often is, on the market during the 180-day exclusivity period. Without competition from other generics, during the 180-day exclusivity period a first filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

61. Once the second wave of generic competitors enter the market, after the first filer's 180-day exclusivity period ends, the competitive process accelerates, multiple generic manufacturers compete vigorously with each other over price, and the price of generics is driven down toward marginal manufacturing costs.²⁰

¹⁹ FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-longterm-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impactreport-federal-trade-commission.pdf> ("FTC 2011 AG Study"); FTC Pay-for-Delay Study, at 1.

²⁰ See, e.g., Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311 (2000).

62. According to the FDA and the FTC, the greatest price reductions happen after the 180-day exclusivity period ends, when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

63. In a 2011 report by the FTC issued at the request of Congress, the FTC found that generics captured 80% or more of sales in the first six months.²¹ (This percentage erosion of brand sales holds regardless of the number of generic entrants.) In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."²²

64. Generic competition enables LEHB and all members of the proposed Class: (a) to purchase generic versions of a drug at substantially lower prices; and/or (b) to purchase the branded drug at a reduced price.

3. Brand manufacturers are incentivized to sell an AG at or slightly in advance of the expiry of a branded drug's patents.

65. Authorized generics, like other generics, compete on price.

66. A brand manufacturer may sell an AG at any time. An AG is chemically identical to the brand but sold as a generic, typically through either the brand manufacturer's subsidiary (if

²¹ FTC 2011 AG Study, at 66-67.

²² See FDA, *Generic Drugs: Questions and Answers*, <http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm> (last visited Jan. 11, 2018).

it has one) or a third-party distributor. An AG is essentially the brand product in a different package, but sold at a lower price.

67. Early in the life of the patents pertaining to a branded drug, the brand manufacturer has little incentive to sell an AG—doing so would simply cannibalize sales from the more profitable brand product. But as the patent nears expiry, and the prospect of generic competition arises, the brand manufacturer’s incentive to sell an AG increases.

68. One study notes that “pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed ‘authorized generics.’”²³

69. Brand manufacturers sometimes begin selling AGs before the first filer generic enters the market so they can secure multiyear purchase contracts with direct purchasers and load the generic pipeline at the expense of the first filer generic.

70. Competition from an AG substantially reduces drug prices and the revenues of the first filer generic (especially during the 180-day exclusivity period).²⁴ A study analyzing three examples of AGs found that “[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand.”²⁵

71. The FTC found that AGs capture a significant portion of sales, reducing the first filer generic’s revenues by about 50% on average.²⁶ The first filer generic makes much less money

²³ Kevin A. Hassett & Robert J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 SONECON (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

²⁴ Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. L. REV. 175, 189 (2007).

²⁵ Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers’ Welfare*, 26 HEALTH AFFAIRS 790, 796 (2007).

²⁶ FTC 2011 AG Study, at 139.

when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

72. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic's 180-day exclusivity period. All drug industry participants recognize this. PhRma recognizes it.²⁷ Generic companies recognize it.²⁸ So do brand companies.²⁹

C. Pharmaceutical Manufacturers Game the Regulatory Structure to Impair Competition.

73. When they do not face generic competition, brand manufacturers can usually sell the brand far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins—without losing so many sales to competitors that the higher price becomes

²⁷ Brand industry group PhRma sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

²⁸ One generic manufacturer stated that “[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the ‘pure’ generic during the exclusivity period could be reduced by approximately 60% in a typical scenario.” See FTC 2011 AG Study, at 81. Another generic quantified the fiscal consequences of competing with an authorized generic version of the brand drug Paxil, determining that the authorized generic reduced its first generic's revenues by two-thirds, or by approximately \$400 million. Comment of Apotex Corp. in Support of Mylan Citizen Petition (Mar. 24, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P=0075-emc00001.pdf>. In 2004, generic company Teva acknowledged that an authorized generic would “severely devalu[e]” its 180-day exclusivity because an authorized generic “effectively transfers much of the profit value from the generic challenger [to the authorized generic]” and “allows the [authorized generic] to seize a significant share of the generic supply chain.” Teva Citizen Petition, Docket No. 2004P-0261/CPI (June 9, 2004), www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf.

²⁹ Commenting on Teva's FDA petition, Pfizer stated: “Teva's petition [to prevent the launch of an authorized generic] is a flagrant effort to stifle price competition – to Teva's benefit and the public's detriment.” Comment of Pfizer at 7, Docket No. 2004P-0261 (June 23, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/062904.htm#04P0261>; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf>.

unprofitable—is what economists call market or monopoly power. When generics enter the market, however, they quickly take 80% or more of the unit sales. And because when multiple generics are in the market, the competition between the generics drives their prices to near the marginal cost of production, this competition puts an end to the brand manufacturer's market or monopoly power and delivers enormous savings to drug purchasers.

74. A brand manufacturer in the marketplace without competition from generics receives all of the profits on all of the unit sales.

75. When the brand manufacturer competes against only the first filer generic manufacturer, they enjoy a duopoly—both tend to sell at close to the monopoly price, and make near-monopoly profits.³⁰

76. When multiple generic manufacturers enter, the brand manufacturer loses most of the unit sales; generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to drug purchasers.

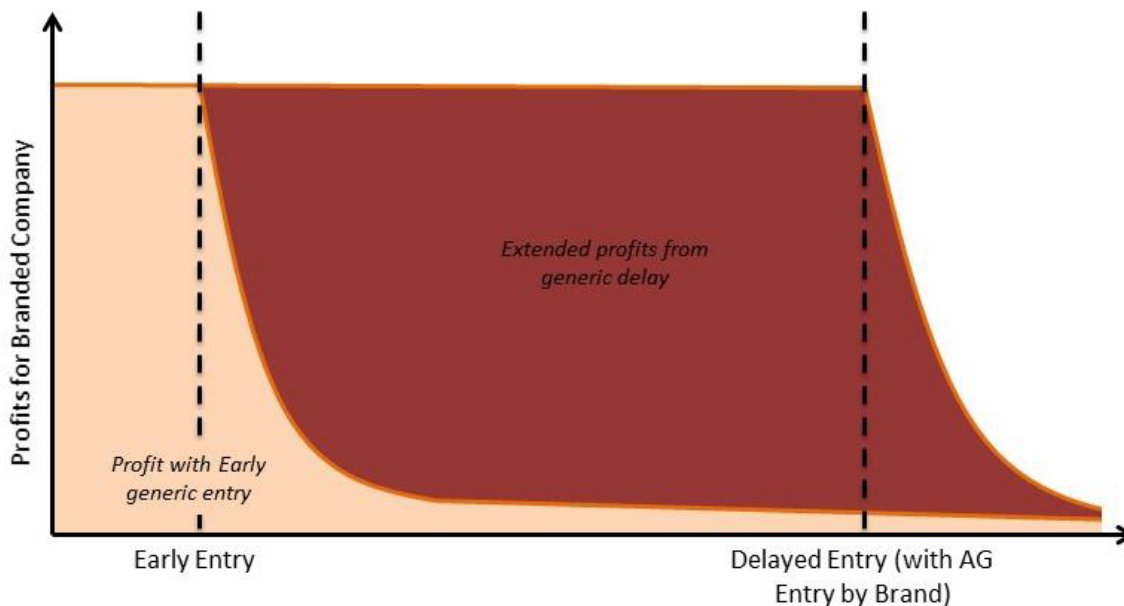
77. Brand and first filer generic manufacturers have a collective interest in preventing this competition from breaking out. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers.

78. To achieve this goal, brand and generic manufacturers sometimes—unlawfully—agree, often but not exclusively in writing, not to compete and instead to split the purchaser savings between themselves.

³⁰ See generally Tony Ellery & Neal Hansen, *Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand* 108 (2012); Benjamin G. Druss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFF. 210, 213-14 (2004).

79. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where the brand manufacturer did not pay-off the generic company to delay generic entry; and (ii) a situation where the brand manufacturer conspires with the generic manufacturer to delay generic drug entry. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly.

Figure 1. Impact of Generic Delay on Brand Profits



80. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains through some means. Pay-offs from the brand manufacturer are the means by which brand and generic manufacturers divide between themselves the ill-gotten gains that delayed competition makes possible. These unlawful pay-off deals are often referred to as “pay-for-delay” or “exclusion payment” agreements.

81. The brand manufacturer may choose to pay off only the first filer, even if other generic manufacturers are also lined up to challenge the patents. The first filer's agreement to delay marketing its drug also prevents other generic manufacturers from marketing their products.

82. Later ANDA filers have more modest financial expectations because they generally anticipate no market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

83. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

84. When an anticompetitive agreement with the first filer is already in place, however, pursuing litigation becomes less attractive to later ANDA filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement) and that they will have to bear the bulk of the litigation costs themselves.

85. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first filer generic and agree to drop their challenges to the brand manufacturer's patent(s) and stay off the market until after entry by the first filer.

86. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's

monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. No-AG agreements enable manufacturers to share the gains from conspiring.

87. In the 1990s, the pay-offs from brand manufacturers often took the form of cash payments to the generic competitor. Since the 2000s, as a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand and generic manufacturers have entered into increasingly more elaborate agreements in an attempt to hide pay-offs.

88. One form of pay-off, at issue here, is a no-AG promise. With a no-AG promise, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters the market.

89. Again, the first filer's ANDA exclusivity does not prohibit the brand manufacturer from marketing its AG under the authority of its NDA. The Hatch-Waxman Amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

90. Absent a no-AG promise, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the first generic enters the marketplace. But competition from an AG has a drastically negative effect on the first filer generic's revenues. Competition from an AG typically cuts the first filer's revenues by more than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower—eliminating the duopoly and delivering commensurate savings to drug purchasers.

91. To prevent an AG from causing this substantial loss of revenues and profits, a first filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG. The additional monopoly profits that

the brand manufacturer gains from the delayed onset of generic competition more than make up for the profits it forgoes by not competing with an AG. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic competition for the first 180 days of marketing. Both manufactures win, but drug purchasers lose.

92. The brand and first filer's reciprocal promises not to compete harm indirect purchasers like LEHB thrice over. The pact delays the first filer's entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. By delaying the first filer's entry, the pact also delays the time when other, later, generics enter, and may discourage their entry altogether. Finally, the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period between the first filer's generic and the brand's AG.

93. For the first filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash.³¹ Courts, including those in this Circuit, agree that no-AG agreements are a form of payment actionable under *FTC v. Actavis* and are anticompetitive.³²

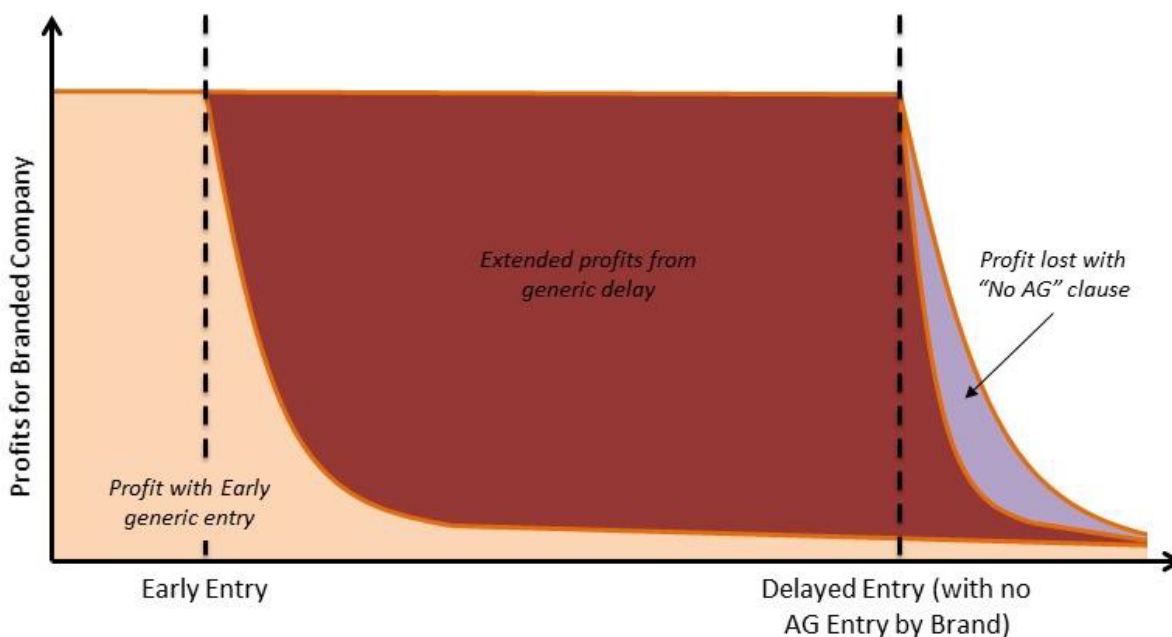
³¹ See, e.g., Press Release, FTC, Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics (June 24, 2009), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf>.

³² See *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549-50 (1st Cir. 2016); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 716-18 (N.D. Ill. 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp's Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

94. For a first ANDA filer (like Par) for a brand drug with millions of dollars in annual sales (like Exforge®), the difference between selling a generic without having to compete against an AG and selling in competition with an AG can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

95. Figure 2 depicts what happens when a brand manufacturer agrees to a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic).

Figure 2. Impact of No-AG Clause on Brand Profits



VII. EXFORGE® CONSPIRACY

A. 1992-2002: Novartis applies for and obtains amlodipine and valsartan patents

96. On December 29, 1992, Novartis filed U.S. Patent Application 998,755, entitled “ACYL Compounds,” which Novartis used to gain exclusivity to manufacture valsartan. The U.S. Patent Office approved the application on March 21, 1995 and issued the ’578 Patent.

97. The ’578 Patent, which disclosed and claimed the chemical compound valsartan, expired on March 21, 2012. A regulatory exclusivity known as pediatric exclusivity³³ attached to the ’578 Patent expired on September 21, 2012.

98. On June 18, 1997, Novartis filed a U.S. Patent Application for the ’197 Patent. In its patent application, Novartis described that the ’197 Patent concerned solid dosage forms comprising (a) valsartan and (b) pharmaceutically acceptable additives suitable for preparing solid oral dosage forms and included fifty-three (53) claims, of which only four were independent claims. The U.S. Patent Office approved the application on September 25, 2001.

99. On January 9, 2001, Novartis filed U.S. Patent Application 09/757,413, entitled “Method of Treatment and Pharmaceutical Composition,” and described how the invention was developed to treat and prevent diseases related to hypertension, high blood pressure and other cardiac related diseases. The U.S. Patent Office approved the application on May 28, 2002 and issued the ’728 Patent.

B. In 2007, Novartis combines amlodipine and valsartan to create a new blood pressure lowering drug

100. High blood pressure and its consequences affect an estimated one in four adults; that is roughly a billion people worldwide. The disorder is the leading cause of risk-attributable

³³ As a result of conducting tests in pediatric age groups, the FDA granted Novartis a six-month regulatory exclusivity called pediatric exclusivity.

death, accounting for more than 7 million deaths per year. A person dies somewhere in the world from a hypertension-related disease every five seconds.

101. Exforge® was the first high blood pressure medication to combine the most commonly prescribed branded high blood pressure medicines in their respective class – Norvasc, the calcium channel blocker amlodipine besylate, and Diovan, the angiotensin-II receptor blocker valsartan. On June 20, 2007, the FDA approved Novartis' NDA for Exforge® tablets. Shortly thereafter, Exforge® tablets were launched into the U.S. marketplace.

102. Novartis already had intellectual property rights to Diovan, but its plan was to combine the active ingredients in Diovan and Norvasc, the latter of which was a Pfizer product, as soon as Pfizer's patents expired in September 2007. On March 22, 2007, however, the Federal Circuit invalidated Pfizer's Norvasc patents, paving the way for earlier FDA approval of Novartis' Diovan/Norvasc combination.

103. Novartis claimed that Exforge®, the combination of valsartan and amlodipine, offered patients the convenience of a reduced pill load for their hypertension medication, increasing patient adherence.

C. Fall 2007: Par and Synthon file ANDAs for generic versions of Exforge®

104. Generic manufacturers Par and Synthon recognized the huge market potential for Exforge® and, in or about the fall of 2007, were the first generic companies to file ANDAs with the FDA containing paragraph IV certifications as to certain Exforge® patents.

105. Par filed ANDA 90-011 on October 1, 2007, for the 10/160, 5/160, 10/320 milligram strengths of Exforge®, and was the first applicant to file a substantially complete application containing a paragraph IV certification for those three strengths, making Par eligible for 180 days of regulatory exclusivity.

106. Synthon filed ANDA 90-144 on November 26, 2007, for the 5/320 milligram strength of Exforge®, and was the first applicant to file a substantially complete application containing a paragraph IV certification for the 5/320 mg strength, making Synthon eligible for 180 days of regulatory exclusivity for that strength.

107. Par and Synthon each addressed the Orange Book-listed Novartis patents for Exforge® in their ANDA filings as follows: (1) each submitted Paragraph III certifications to the '578 Patent (meaning that they would not seek to market a generic product prior to the expiration of that patent); and (2) each submitted paragraph IV certifications to the '197 and '728 Patents (meaning they sought to enter into the market prior to the expiration of those patents, which they claimed were invalid, unenforceable, and/or would not be infringed by Par's or Synthon's generic products). Therefore, on or shortly after October 1, 2007 and November 26, 2007, respectively, Par and Synthon disclosed their intentions to market their AB-rated generic products as early as September 21, 2012.

108. Because Par and Synthon were the first companies to file substantially complete ANDAs with paragraph IV certifications, they stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. 355(j)(5)(B)(iv): 180 days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Exforge®.

109. After receiving confirmation of receipt from the FDA for their respective ANDAs, Par and Synthon each sent notice to Novartis of their ANDAs containing paragraph IV certifications that included "a detailed factual and legal statement as to why" the '197 and '728 Patents were "invalid, unenforceable, and/or not infringed" by Par's and Synthon's ANDA Products (the "Paragraph IV Notices"). The Paragraph IV Notices each included an offer of

confidential access to Par's and Synthon's ANDAs as required under Hatch-Waxman. The Notices gave rise to a cause of action by Novartis for infringement under the Hatch-Waxman Act.

D. 2010: The FDA grants tentative approval of Par's ANDA for the generic version of Exforge®

110. On March 19, 2010, the FDA granted tentative approval to Par's ANDA for the generic version of Exforge®, indicating its determination that Par's generic Exforge® was approvable and satisfied all bioequivalence, chemistry, manufacturing, and controls ("CMC"), and labeling requirements.

E. Novartis does not file suit against Par or Synthon, and even if it had, Novartis would have been unsuccessful

111. Within 45 days of receiving Par's Paragraph IV Notices related to the '197 and '728 Patents, the Hatch-Waxman framework permitted Novartis, the patent holder, to sue Par, the generic manufacturer, for patent infringement. If Novartis had filed suit against Par, an automatic 30-month stay of FDA approval is instituted (commonly called a 30-month Hatch-Waxman stay).

112. After receiving Par's and Synthon's Paragraph IV Notices, Novartis did not file a lawsuit against either Par or Synthon for infringement of the '197 and '728 Patents within the 45-day time period set forth in the statute to trigger a 30-month stay of ANDA approval. Accordingly, no 30-month stay ever went into effect for the Par or Synthon ANDAs.

113. Since Novartis did not sue to enforce its patents, as of March 19, 2010, the only thing preventing Par and Synthon from obtaining final FDA approval and launching its generic Exforge® was the last few years of protection afforded by the '578 Patent covering the active ingredient valsartan.

114. The fact that Novartis never sued Par on the '197 or '728 Patents reflects Novartis' belief that those patents did not afford Novartis any right to exclude Par from marketing its generic version of Exforge®.

115. Evidence of the weakness of the '197 and '728 Patents includes, but is not limited to:

- a. Par's and Synthon's ability to develop and file ANDAs with Paragraph IV Notices within a few months of FDA's approval of Exforge®;
- b. Novartis' decision not to sue for patent infringement to enforce its intellectual property in court; and
- c. The facts set forth above and in Par's and Synthon's Paragraph IV Notices.

1. The '728 Patent is invalid

116. No valid claim of the '728 Patent was infringed by Par's filing of ANDA No. 90-011 or the manufacture or sale of Par's generic version of Exforge®. First, the claims of the '728 Patent are properly construed to be limited to the use of a combination of valsartan and amlodipine for the treatment of hypertension in the limited subset of patients suffering from diabetes and could not have afforded Novartis any right to exclude generic competition beyond that very narrow use. The '728 Patent issued from U.S. Application No. 09/757,413 (the "'413 Application"), which is a divisional of U.S. Application No. 09/349,654 (the "'654 Application").

117. The original claims of the '654 Application broadly recited (1) "[a] method for the treatment or prevention of [a wide variety of different disease states] comprising administering a therapeutically effective amount of a combination" of valsartan and a pharmaceutically acceptable carrier; and (2) "[a] pharmaceutical combination composition comprising" those same ingredients. '654 Application at 11.

118. The examiner at the U.S. Patent Trademark Office ("PTO"), however, rejected each of those claims as obvious in view of U.S. Patent No. 5,492,904 ("the '904 Prior Art Patent") and the prescribing information for Diovan ("the Prior Art Diovan Literature"). Office Action dated May 25, 2000. The U.S. PTO examiner noted that the '904 Prior Art Patent taught the combined use of an angiotensin-II antagonist (like valsartan) and a calcium channel blocker (like amlodipine)

“teach[es] pharmaceutical compositions which comprise an angiotensin-II antagonist and a calcium channel blocker of the type presently claimed which are useful in the treatment of hypertension and congestive heart failure. . . [and] that the compositions may comprise from 10 to 300 mg of the desired calcium channel blocker and from 1 to 100 mg of the angiotensin-II antagonist.” *Id.* at 2. The U.S. PTO examiner acknowledged that the ’904 Prior Art Patent did not reach valsartan, but noted that the Prior Art Diovan Literature “disclose[d] that valsartan was a well-known angiotensin-II antagonist.” *Id.* Accordingly, the examiner deemed the originally-claimed subject matter to be obvious. *Id.* at 3.

119. The applicants for the ’654 Application amended their method of use claim 1 by deleting the broad recitation of disease conditions and narrowing it to the treatment of “hypertension *associated with diabetes*.” Amendment After Final Rejection dated October 20, 2000 at 1-2 (emphasis added). Thereafter, the ’654 Application issued as United States Patent No. 6,204,281.

120. The ’413 Application was filed as a divisional application on January 9, 2001, along with a preliminary amendment whose claims were similar to those that had been originally filed in the ’654 Application. The U.S. PTO examiner rejected the claims pending in the ’413 Application as obvious for the same reason he had rejected the claims in the ’654 Application. April 27, 2001 Office Action at 3. In response to the rejection, and consistent with their amendment to the ’654 Application, the applicants limited claim 1 of the ’413 Application to the treatment of “hypertension associated with diabetes.” Amendment dated July 25, 2001 at 3. In explaining why the amendment would overcome the examiner’s obviousness rejection, which applied to all pending claims, including the method claims, the applicants argued that they had shown unexpected results in the treatment of diabetes. *Id.* at 4. Thus, while the “composition of matter”

claims did not refer explicitly to diabetes, the applicants' argument was premised on the view that those claims were also limited to the use of the claimed pharmaceutical composition in patients suffering from diabetes. *Id.* ("Claims 1-9 have been rejected Applicants respectfully traverse this rejection. *The claims are now directed to hypertension associated with diabetes.*") (emphasis added).

121. The U.S. PTO examiner nevertheless again rejected the claims. Office Action dated August 1, 2001. In response, the applicants further amended the claims to limit them to the use of valsartan with amlodipine. In doing so, they again made clear that both the method of use and composition of matter claims should be viewed as limited to the use in the "treatment of hypertension associated with diabetes." Amendment After Final Rejection dated September 24, 2001.

122. Par was not seeking FDA approval to market its product for the treatment of hypertension associated with diabetes, and therefore it's ANDA did not infringe on the '728 Patent.

123. In addition, the claims of the '728 Patent are invalid in view of the prior art. The '904 Prior Art Patent was issued on February 20, 1996, more than three years before the earliest possible effective filing date of the '728 Patent. The '904 Prior Art Patent is also related to hypertension related with diabetes. Specifically, it teaches that "[t]he combinations of this invention can be administered for the treatment of hypertension" and that the "[p]harmaceutical compositions of the invention may contain from 10 to 300 mg of the desired calcium channel blocker and 1 to 100 mg of the angiotensin-II receptor antagonist per unit dose one or more times daily." '904 Prior Art Patent at 4:4-5 and 44-48. The '904 Prior Art Patent also references certain disease states involving "diabetic" conditions. *Id.* at 3:56-4:3.

124. Although the '904 Prior Art Patent does not explicitly reference valsartan, that is unsurprising. The patent application that issued as the '904 Prior Art Patent was filed on July 28, 1994, whereas the prior art '578 Patent disclosing valsartan did not issue until March 21, 1995. Thus, the '904 Prior Art Patent was filed before valsartan was publicly disclosed by the '578 Patent. As soon as the '578 Patent was issued and disclosed valsartan, however, it would have been obvious to use valsartan as the angiotensin-II receptor antagonist in the combination treatment taught by the '904 Prior Art Patent.

2. Par's ANDA does not infringe on the '197 Patent

125. No valid claim of the '197 Patent was infringed by Par's filing of ANDA No. 90-011 or the manufacture or sale of Par's generic version of Exforge®. The '197 Patent issued on September 25, 2001 from an application filed on June 18, 1997. The '197 Patent includes fifty-three (53) claims, of which only four are independent claims. "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553, 10 USPQ2d 1201, 1208 (Fed. Cir. 1989). Each of the independent claims in the '197 Patent requires a compressed solid dosage form (or a process for forming or method of using such a compressed solid dosage form) comprising either (1) greater than 35% by weight valsartan; and/or (2) the active ingredient hydrochlorothiazide ("HCTZ") in combination with valsartan. Neither Exforge® nor any generic version of Exforge® contains or could contain the active ingredient HCTZ. Accordingly, the claims of the '197 Patent could cover a generic version of Exforge® only if valsartan were present at greater than 35% by weight of the dosage form. On information and belief, at all relevant times Par's generic version of Exforge® contained less than 35% by weight valsartan, and thus could not literally infringe any of the claims of the '197 Patent.

126. As a matter of law, the claims of the '197 Patent cannot cover generic versions of Exforge® that contain 35% or less by weight valsartan under the doctrine of equivalents. First, “[a] doctrine of equivalents theory cannot be asserted if it will encompass or ‘ensnare’ the prior art.” *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017). Here, the '578 Patent is prior art to the '197 Patent and discloses a tablet that is 35.7% by weight valsartan. '578 Patent at 63:24-52 (example 93). Any doctrine of equivalents theory that encompassed a compressed solid dosage form having 35% or less valsartan would therefore improperly cover the prior art. Second, “[i]f a theory of equivalence would vitiate a claim limitation . . . then there can be no infringement under the doctrine of equivalents as a matter of law.” *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998); *see also Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (“[T]o allow what is undisputedly a minority (i.e., 47.8%) to be equivalent to a majority would vitiate the requirement that the ‘first and second longitudinal strips of adhesive . . . extend the majority of the lengths of said longitudinal marginal portions.’”). Here, allowing a claim limitation that requires solid dosage forms comprising “more than” 35% by weight valsartan to cover solid dosage forms having “less than” 35% by weight valsartan would vitiate a claim limitation and would therefore be improper.

127. In addition, the relevant claims of the '197 Patent are invalid. The earliest effective filing date for the '197 Patent is June 18, 1997, and therefore, the '578 Patent that issued on March 21, 1995 is prior art to the '197 Patent. Claim 1 of the '197 Patent, for example, recites the following:

1. A compressed solid dosage form comprising a) an active agent containing an effective amount of Valsartan or a pharmaceutically acceptable salt thereof; and, b) at least one pharmaceutically acceptable additive wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid dosage form.

'197 Patent at 10:22-30. The '578 Patent anticipates this claim, thereby rendering it invalid. '578 Patent at 63:25-52 (example 93). More specifically, the prior art '578 Patent teaches a tablet (*i.e.*, a compressed solid dosage form) comprising 35.7% valsartan and a number of pharmaceutically acceptable additives including, for example, lactose. *Id.*

128. The U.S. PTO examiner apparently did not understand that example 93 of the '578 Patent related to valsartan. Valsartan is a generic name for the chemical compound (S)-N-(1-carboxy-2-methylprop-1-yl)-N-pentanoyl-N-[2'-(1H-tetrazol-5-yl)-biphenyl-4-ylmethyl-] amine. The '578 Patent does not use the term "valsartan" but rather referred to the compound by its chemical name. Had the examiner understood that that example 93 of the '578 Patent referred to valsartan, he would have rejected claim 1 under 35 U.S.C. § 102.

129. Rather than disclose to the examiner that example 93 of the '578 Patent related to valsartan, the applicants exploited the examiner's lack of appreciation. For example, when the examiner rejected the claims based on a different prior art reference, the applicants made arguments that could not have been made had the examiner appreciated example 93 of the '578 Patent.

130. Novartis knew Par and/or Synthron would have won a patent infringement lawsuit had Novartis filed one. Thus, since it had weak patent claims, Novartis was desperate to avoid an adverse ruling on its patents.

F. 2011: Novartis enters into an agreement with Par

131. Instead of suing Par, Novartis entered into an agreement with Par, whereby Par would abandon its efforts to launch at the earliest possible date after the expiration of the '578 Patent and instead would launch no earlier than September 30, 2014, almost exactly two years after expiry of the '578 Patent (the "Anticompetitive Agreement"). The Anticompetitive

Agreement also provided that Novartis would not launch an AG for the first six months after Par's entry into the generic Exforge® market.

132. On information and belief, Novartis was motivated to enter into the Anticompetitive Agreement because it had weak patent claims and because it would rather enter into a pay-for-delay, no-AG agreement than risking an adverse ruling on its patents.

133. But for the Anticompetitive Agreement, Par would have been prepared, able, and willing to launch generic Exforge® as early as September 21, 2012, but no later than March 29, 2013, and would have communicated as much to the FDA and requested final approval for its ANDAs well in advance of September 21, 2012.

134. By 2009, Exforge® was already generating hundreds of millions of dollars per year in revenues for Novartis. Losing a substantial portion of that revenue stream upon expiry of the '578 Patent – as Novartis would have if the '197 and '728 Patents were held by a court to be invalid, unenforceable, or not infringed, or if Par launched upon final FDA approval after expiry of the '578 patent – would have drastically affected Novartis' profits. Thus, Novartis had enormous incentives to avoid patent infringement litigation and to avoid competition from Par by entering into the Anticompetitive Agreement.

135. Important details of the Anticompetitive Agreement were not disclosed until years after it was reached. For example, a January 2012 analyst day presentation by Par lists a "Synthon/Exforge®" "Business Development" arrangement in 2011. Additionally, Par's 10-K for the fiscal year ending December 31, 2011 states "[o]n November 30, 2011, we entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc., and on December 30, 2011, we closed on our acquisition, of Synthon's ANDA for amlodipine besylate and valsartan (5 mg/320 mg and 10 mg/320 mg) fixed dose combination tablets, a generic version of Exforge®, for \$9,600

thousand. *Under the terms of a separate license agreement with Novartis Pharmaceuticals Corporation, we have a certain launch date in October 2014.*” (emphasis added). Similarly, Novartis’ 20-F for the fiscal year ending December 31, 2011 states “In the US, under a license agreement with a generics manufacturer, the product [Exforge®] is expected to face generic competition beginning in October 2014.”

1. The Anticompetitive Agreement was a payment to Par from Novartis

136. For Novartis, the benefits of the no-AG agreement were enormous. While it would forgo six months of profits on an authorized generic, in turn it would enjoy more than two years of monopoly profits selling much more expensive and profitable branded Exforge®.

137. The Anticompetitive Agreement benefitted Par by guaranteeing that it would be the sole generic on the market during the 180-day exclusivity period, even if it started as early as September 21, 2012 with the expiration of the ’578 Patent. This more than doubled Par’s anticipated sales revenues in the exclusivity period because: (1) Par would capture all or substantially all of the sales that would have gone to the AG, and (2) Par would be able to charge significantly higher prices for its generic product without price competition from the AG. In addition, Par also benefited by delaying its launch of generic Exforge® from September 21, 2012 to September 30, 2014 because Novartis could continue raising prices during that time, making the market more lucrative to divide once Par did enter.

138. At this pre-discovery stage, the value of the pay-for-delay agreement between Novartis and Par can be calculated using the known economics of the pharmaceutical industry.

139. The Anticompetitive Agreement was entered into at some time before 2011. That agreement delayed Par’s generic entry until September 30, 2014.

140. By 2011, when Defendants entered into the Anticompetitive Agreement, other than the expiration of the ’578 Patent which was set to expire on September 21, 2012, no other

impediments existed to the prompt approval and launch of generic Exforge®. First, Par's ANDA had already received FDA tentative and final approval. Second, no other patents held by Novartis would forestall generic entry. Third, as evidenced by Par's ANDA and other announcements it made, Par would be ready and able to launch a generic Exforge® product by September 21, 2012.

141. Absent the pay-for delay agreement between Novartis and Par, generic entry would have occurred much sooner than it did—as early as September 21, 2012—on a date to be determined by the jury at trial.

142. Without the Anticompetitive Agreement, several additional generics would have come to market after Par's 180-day exclusivity ended, as early as March 21, 2013, and in any event much earlier than March 30, 2015.

143. In the absence of the Anticompetitive Agreement, Novartis would have launched its authorized generic version of Exforge® at or around the same time that Par launched its generic as early as September 21, 2012.

2. The value of the Anticompetitive Agreement to Novartis

144. With generic entry into the Exforge market in September 2012, Novartis would have lost about 80% of its branded sales. Without generic entry, it kept all those sales and continued to enjoy those branded sales for an additional two years.

145. Because Par was the first ANDA filer, its agreement not to launch generic Exforge® until September 2014 created a competition bottleneck wherein no other generic company could market a generic Exforge® product until 180 days after Par launched its generic product. By acting in concert with Par to create this bottleneck, Novartis maintained its monopoly on Exforge® for two years longer than it otherwise would have.

146. Determining the value to Novartis of the Anticompetitive Agreement is a matter of estimating the additional branded sales it enjoyed during that two-year delay compared to the sales

it would have made (a) from the reduced sales of branded Exforge® from September 2012 to March 2015, plus (b) the sales of its authorized generic during the same two-and-a-half-year period.

3. The value of the Anticompetitive Agreement to Par

147. Determining the value of the no-AG agreement from Par's perspective requires estimating the additional sales Par made during the six-month generic exclusivity period in 2014-2015 compared to the sales it would have made in the first six months of generic competition starting in September 2012 when, without the benefit of the no-AG agreement, it would have faced competition from Novartis' authorized generic.

148. Under competitive conditions, the calculation of Par's sales during the first six months of generic competition starting, in September 2012, is identical to the calculation for Novartis' AG during this period, because the same assumptions apply to Par's generic as to Novartis'.

149. Under the anticompetitive conditions of the no-AG promise, however, Par stood in a far better position financially. It (a) got 100% (not 50%) of the generic sales in the first six months of generic launch (because there was no authorized generic taking market share); (b) was able to sell that generic during those months for about 90% (not 50%) of the branded price (because there was no authorized generic driving down price); and (c) was able to bring its generic product to a market that had grown in size over the two-year delay period. Indeed, by 2014, annual sales of branded Exforge® had grown to \$400 million.

150. Thus, the no-AG provision represented a very large payment to Par. Specifically, as early as May 2006, financial analysts and media were projecting annual peak sales for Exforge® of \$500 million. During Novartis AG's third quarter, 2007 earnings call, Thomas Ebeling, the CEO of its pharma division, expressed optimism that Exforge® would become a "blockbuster drug" in

the United States, which is an industry designation for drugs that reach \$1 billion in sales. By 2014, Novartis's annual Exforge® sales indeed exceeded \$400 million. Using the most conservative of these numbers, Defendants could assume that 6 months of sales would generate revenue of at least \$200 million ($6/12 \times \400 million).

151. Since the first generic is generally expected to take 80% (or more) of the brand sales, approximately \$160 million worth of brand sales would be converted to the generic ($\$200 \text{ million} \times 0.8$). With only one generic on the market, the generic is typically priced at 90% of the brand, which would result in generic sales of approximately \$144 million ($\$160 \text{ million} \times .9$).

152. Thus, the sales revenue during the 180-day exclusivity period that would reasonably have been anticipated by Par under the Anticompetitive Agreement would be approximately \$144 million.

153. Par's expectations would have differed dramatically if Novartis had not promised to refrain from competing with its own AG. According to an FTC study of the dynamics of authorized generic entry during the 180 day generic exclusivity period, the addition of an AG drives the average generic price down to 52% of the brand price.³⁴

154. Thus, while the generics would still take 80% of brand sales, or \$160 million, the generic sales value would drop to \$83.2 million ($\$160 \text{ million} \times 0.52$). And, it would reasonably be expected that those sales would be split evenly between Par's generic and Novartis' AG.³⁵ Thus, without the no-AG Agreement, Par's expected share of the revenue from sales of generic Exforge® during the first 6 months would be approximately \$41.6 million ($\$83.2 \text{ million} \times .5$).

³⁴ <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>.

³⁵ *Id.* at vi (The Federal Trade Commission has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition).

155. As a result, the expected value at the time of the Anticompetitive Agreement to Par of having no-AG versus facing competition from an AG would have been at least approximately \$102.4 million (\$144 million - \$41.6 million). Thus, Novartis' agreement to not launch an AG for 6 months constituted a payment to Par of \$102.4 million or more. The value of this payment to Par was no different than if Novartis had handed \$102.4 million to Par in cash.³⁶

G. 2013: The FDA grants final approval

156. On March 28, 2013, the FDA granted final approval to Par's ANDA for a generic version of Exforge®. On information and belief, the FDA granted tentative approval to Synthon's ANDA for a generic version of Exforge® prior to March 28, 2013, determining that Synthon's ANDA for generic Exforge® was approvable and satisfied all bioequivalence, CMC, and labeling requirements.

H. 2014: Par launches a generic version of Exforge®; Novartis does not

157. Par's ANDA received final FDA approval to launch a generic version of Exforge® on March 28, 2013.

158. On September 30, 2014, Par launched its generic Exforge®, which, at that time, was the first and only generic form of Exforge® available in the United States.

159. From September 30, 2014 through March 30, 2015, Par's generic Exforge® product was the only generic version of Exforge® sold in the U.S. market.

³⁶ The Federal Trade Commission has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition. FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT vi (2011), available at <http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf>. The Supreme Court has recognized this as well. *See Actavis*, 133 S. Ct. at 2229 (2013) (the "vast majority of potential profits for a generic drug manufacturer materialize during" the first six months of marketing).

160. From September 30, 2014 through March 30, 2015, Novartis was permitted to sell a generic version of Exforge® in competition with Par's generic Exforge® product. However, Novartis did not launch an authorized generic version of Exforge® during Par's 180-day exclusivity period.

161. Novartis, which owns the generic company Sandoz, Inc., which often launches authorized generics, has a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. The FTC has found that, in the time period from 2001 to 2008, which would encompass the Anticompetitive Agreement, here, only three companies launched more authorized generics than Novartis.³⁷

162. Novartis has stated in public SEC filings that “[t]he company that launches an authorized generic typically launches its product at the same time as the generic exclusivity holder.”

163. On information and belief, Novartis has launched at least sixteen authorized generics between 2005 and 2016, including authorized generic versions of Exelon, Famvir, Focalin XR, Lescol XL, Lopressor HCT, Lotrel, Patanase, Patanol, Ritalin, Ritalin SR, Sandostatin, Tegretol XR, Tobi, Tobradex, Trileptal, and VivelleDot.³⁸

164. It is economically rational for a brand manufacturer that intends to launch an AG to do so contemporaneously with the first ANDA filer's launch. The Supreme Court has observed

³⁷ See FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (Aug. 2011), available at <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf> at p. 16 (“For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.”).

³⁸ See FDA's Listing of Authorized Generics as of March 28, 2018, available at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605>.

that “the vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.” *Actavis*, 133 S. Ct. at 2229.

165. Upon information and belief, Novartis would have launched an authorized generic version of Exforge® upon market entry by Par in the absence of the Anticompetitive Agreement here.

166. Until Novartis failed to launch an AG upon market entry by Par in September of 2014, it was not clear that Novartis intended to forgo such a launch, as important details of the license agreement between Novartis and Par were concealed. As set forth above, the six months of delay from Par’s launch in Novartis’ launch of an AG constituted consideration to Par.

167. Even with the most conservative estimates, the payment flowing from Novartis to Par via the Anticompetitive Agreement not to compete with an AG, thereby foregoing the 30-month stay, and Novartis not suing for patent infringement, had a cash value in excess of a hundred million dollars. The payment was to induce Par to stay out of the market for Exforge® and its generic equivalents in return for sharing monopoly profits among Defendants.

I. March 2015: 180 days after Par’s generic Exforge® launches, more generics launch

168. On or about on March 30, 2015 – the day Par’s period of exclusivity expired – Mylan, N.V. (“Mylan”), Teva Pharmaceutical Industries, Ltd. (“Teva”), Torrent Pharms, Ltd. (“Torrent”), Novel Labs, Inc. (“Novel”) and Lupin Pharmaceuticals, Inc. (“Lupin”) received final approval from the FDA and launched generic versions of Exforge®.

169. On information and belief, Mylan, Teva, Torrent, Novel, and Lupin launched without a license from Novartis, despite the fact that the ’197 and ’728 patents had not yet expired. Novartis also would have launched its AG upon Par’s launch.

170. According to information available publicly through the FDA, in addition to Par and Synthon, at least eight additional companies filed ANDAs to sell generic Exforge®:

Application No.	Company
202713	Alembic Pharms Ltd
206512	Aurobindo Pharma Ltd
205137	Invagen Pharms
090245	Lupin
090483	Mylan Pharms Inc.
202829	Novel Labs Inc
091235	Teva Pharms USA
202377	Torrent Pharms Ltd

171. Also according to information available publicly through the FDA, many of these entities received final approval on or around the end of Par's actual 180-day exclusivity of March 30, 2015.

172. Thus, Par launched its generic product as early as September 21, 2012, but no later than March 28, 2013, at least one subsequent filer, and likely several, would have obtained final FDA approval and launched its generic equivalent of Exforge® immediately upon expiration of Par's 180-day exclusivity period.

173. But for Defendants' ongoing performance under the Anticompetitive Agreement, generic competition for Exforge® would have occurred earlier and prices for both branded and generic versions of Exforge® would have been lower. Because generic versions of Exforge® would have become available as early as September 21, 2012, but no later than March 29, 2013. Plaintiff and other members of the Class would have paid lower prices for Exforge® and its generic equivalents. Defendants, by their conduct, have injured Plaintiff and other members of the Class by causing them to pay millions of dollars in overcharges on their purchases of Exforge® and its generic equivalents.

VIII. THE SCHEME'S EFFECTS ON COMPETITION AND HARM TO LEHB AND THE CLASS

174. Novartis' and Par's unlawful agreement impaired and delayed the sale of generic Exforge® in the United States and unlawfully enabled Novartis to sell its branded Exforge® at artificially inflated prices, and then allowed Par to sell its generic Exforge® at artificially inflated prices. But for Novartis' and Par's unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Exforge®, at a much earlier date.

175. But for Defendants' anticompetitive conduct, LEHB and other members of the Class would have: (1) purchased lower-priced generic, AB-rated Exforge®, instead of the higher priced brand Exforge®, during the period when Par delayed its entry to the market; (2) paid a lower price for generic Exforge® products during Par's 180-day exclusivity period; and (3) paid lower prices for generic Exforge® products, as a result of the entry of generics at an earlier date, sooner.

176. As a consequence, LEHB and other indirect purchasers have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

IX. MARKET POWER AND DEFINITION

177. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. This disconnect is created by state laws that prohibit pharmacists from dispensing many pharmaceutical products, including Exforge®, to patients without a prescription.

178. Brand manufacturers, including Novartis, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the

branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in selection between branded products.

179. The lack of both transparency of, and sensitivity to, price in the pharmaceutical marketplace reduces the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs without losing sales sufficient to defeat the price increases is what economists and antitrust courts refer to as market or monopoly power. The result of these pharmaceutical-market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Exforge®.

180. Before September 21, 2012, Novartis had monopoly power in the market for Exforge® and its AB-rated generic equivalents because it had the power to exclude competition and/or raise or maintain supra-competitive prices without losing enough sales to make those prices unprofitable. Due to the unlawful pay-for-delay agreement, Novartis continued to have that monopoly power in the market for Exforge® and its AB-rated generic from September 21, 2012 through September 30, 2014. From September 30, 2014 to March 30, 2015, Novartis and Par combined had substantial market power in the market for Exforge® and its generic equivalent, because they had the power to exclude competition and/or to raise or maintain the price of fixed combination products comprising amlodipine and valsartan at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

181. At all relevant times, a small but significant, non-transitory increase to the price of Exforge® and its AB-rated generic equivalents would not have caused a loss of sales sufficient to make that increase unprofitable.

182. Novartis (and, later, Novartis and Par) needed to control only brand Exforge® and its AB-rated generic equivalents, and no other products, to maintain supra-competitive prices. Only the market entry of competing, AB-rated generic versions would render Defendants unable to maintain profitably their prices for Exforge® and its AB-rated generic equivalents—of which Par's was the only one during the 180-day exclusion period—without losing substantial sales.

183. During the 180-day exclusion period, Novartis sold brand Exforge® and Par sold generic Exforge® at prices well in excess of marginal costs and in excess of the competitive price, and, therefore, Novartis and Par enjoyed high profit margins.

184. Defendants had, and exercised, the power to exclude generic competition to Exforge® and its AB-rated generic equivalents.

185. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Exforge® and, in turn, Par's generic Exforge®, from the forces of price competition.

186. Direct evidence of market power and anticompetitive effects available in this case obviates the need to establish a relevant antitrust market. This direct evidence of Defendants' ability to control the price of Exforge® and generic Exforge®, and to exclude ready, willing entrants, consists of, *inter alia*, the following facts: (a) Novartis' gross margin on Exforge® (including the costs of ongoing research/development and marketing) at all relevant times was very high; (b) Novartis never lowered the price of Exforge® to the competitive level in response to the pricing of other brand or generic drugs other than the AB-rated generic Exforge®; and (c) a

generic Exforge® seller would have entered the market at a much earlier date, at a substantial discount to brand Exforge®, but for Defendants' anticompetitive conduct.

187. To the extent proof of monopoly power by defining a relevant product market is required, LEHB alleges that the relevant antitrust market is the market for Exforge® and its AB-rated generic equivalents.

188. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

189. Novartis' market share in the relevant market was 100% until September 30, 2014, after which Novartis and Par collectively had 100% market share in the relevant market until March of 2015, when Teva, Mylan, Torrent, Novel and Lupin all launched generic Exforge® products.

X. ANTICOMPETITIVE EFFECTS

190. Defendants willfully and unlawfully maintained their market power by engaging in a conspiracy to exclude competition. Defendants designed a scheme to delay competition on the merits, to further Novartis' anticompetitive purpose of forestalling generic competition against Exforge®, in which Novartis and Par cooperated to increase their own profits. Novartis and Par carried out the scheme with the anticompetitive intent and effect of maintaining supra-competitive prices for Exforge® and its AB-rated generic equivalents.

191. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Exforge®, and later Par's generic Exforge®, from competition. These actions allowed Defendants to maintain a monopoly and to exclude competition in the market for Exforge® and its AB-rated generic equivalents, to the detriment of Plaintiff and all other members of the Class.

192. Defendants' exclusionary conduct delayed generic competition and unlawfully enabled Novartis and Par to sell Exforge® without further generic competition. Were it not for Defendants' illegal conduct, Par's generic would have faced competition during Par's 180-day exclusivity period from a Novartis authorized generic, and one or more additional generic versions of Exforge® would have entered the market sooner.

193. Defendants' illegal acts and conspiracy to delay generic competition for Exforge® caused LEHB and all members of the Class to pay more than they would have paid for Exforge® and its AB-rated generic equivalents absent this illegal conduct.

194. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, indirect purchasers, such as LEHB and members of the Class, would have paid less by (a) paying lower prices on their brand purchases of Exforge®, (b) substituting purchases of less-expensive generic Exforge® for their purchases of more-expensive brand Exforge®, and/or (c) purchasing generic Exforge® at lower prices, sooner.

195. Thus, Defendants' unlawful conduct deprived LEHB and members of the Class of the benefits from the competition that the antitrust laws are designed to ensure.

XI. ANTITRUST IMPACT AND INTERSTATE COMMERCE

196. During the relevant time period, Defendants manufactured, sold, and shipped Exforge® and generic Exforge® across state lines in an uninterrupted flow of interstate commerce.

197. During the relevant time period, LEHB and members of the Class purchased substantial amounts of Exforge® and/or generic Exforge® indirectly from Defendants. As a result of Defendants' illegal conduct, LEHB and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

198. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged herein, within the flow of, and substantially affecting, interstate commerce.

199. During the class period, each Defendant, or one or more of each Defendant's affiliates, used the instrumentalities of interstate commerce to join or to effectuate the scheme. The conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

XII. EFFECT ON INTRASTATE COMMERCE

200. During the relevant time period, branded Exforge®, manufactured and sold by Novartis, was shipped into each state and was sold to or paid for by indirect purchasers. Beginning around September 30, 2014, generic Exforge®, manufactured and sold by Par, was shipped into each state and was sold to or paid for by indirect purchasers.

201. During the relevant time period, in connection with the purchase and sale of branded Exforge®, money exchanged hands and business communications and transactions occurred in each state. Beginning September 30, 2014, in connection with the purchase and sale of generic Exforge®, money exchanged hands and business communications and transactions occurred in each state.

202. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper Exforge® and generic Exforge® to indirect purchasers purchasing inside each respective state, and Defendants entered into an unlawful Anticompetitive Agreement that affected commerce in each state.

XIII. DEFENDANTS' FRAUDULENT CONCEALMENT TOLLED THE APPLICABLE STATUTES OF LIMITATIONS AND DELAYED ACCRUAL OF LEHB'S CAUSES OF ACTION

203. A cause of action accrued for LEHB and the Class each time LEHB or members of the Class paid for or reimbursed a purchase of Exforge® or its generic equivalent at a supra-competitive price made possible by Defendants' anticompetitive conduct. The September 2014 launch by Par, Novartis' forgoing a launch of an AG at that time, and each sale by Defendants of a product at a supra-competitive price constitute overt acts in furtherance of their anticompetitive scheme. Accordingly, LEHB and the Class are entitled to recover all damages on all sales that Defendants made to them at supra-competitive prices.

204. Due to Defendants' concealment of the terms of the Anticompetitive Agreement, LEHB and members of the Class are entitled to recover damages reaching back beyond any limitations periods otherwise applicable to their claims, because the earliest they could reasonably have learned of Defendants' conspiracy was in September 2014, when Par began selling generic Exforge® and Novartis did not respond with an AG. Novartis and Par had earlier disclosed only cursory information about the existence of the Anticompetitive Agreement. LEHB and members of the Class had no knowledge of Defendants' unlawful scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence, nor did they have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed, or believe in good faith that a violation had been committed, until September 2014.

205. This is true because the nature of Defendants' scheme was self-concealing and because Defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to conceal, their contract, combination, conspiracy and scheme.

206. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from LEHB and members of the Class by, among other things:

- a. Concealing the fact of Novartis' agreement not to launch a competing authorized generic Exforge® product in exchange for Par's agreement not to market its competing generic product until September 30, 2014;
- b. Concealing the fact that the purpose of the Anticompetitive Agreement was to provide compensation in connection with the September 30, 2014 entry date for Par's generic product; and
- c. Filing documents with the United States Securities and Exchange Commission that provided only limited information about the existence or nature of the Anticompetitive Agreement and the payments made.

207. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting LEHB's and members of the Class' claims have been tolled, and the accrual of LEHB and members of the Class' causes of action have been delayed.

208. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and the members of the Class can recover for damages that they suffered during the limitations period. *See supra* Section IV.

XIV. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF Conspiracy and Combination in Restraint of Trade Under State Law (Against All Defendants)

209. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

210. Defendants entered into an unlawful pay-for-delay agreement that restrained competition in the market for Exforge® and its AB-rated generic equivalents. Their agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

- a. delay entry of generic Exforge® in order to lengthen the period in which Novartis's brand Exforge® could monopolize the market and make supra-competitive profits;
- b. keep an Exforge® AG off the market during Par's 180-day generic exclusivity period, thereby allowing Par to monopolize the generic market for Exforge® during that period and allowing Par to make supra-competitive profits;
- c. allocate 100% of U.S. generic Exforge® sales to Par during the first 180 days of generic sales; and
- d. raise and maintain the prices that Plaintiff and the members of the Class would pay for Exforge® to and at supra-competitive levels.

211. Defendants' Anticompetitive Agreement harmed LEHB and the members of the Class as set forth above.

212. There is no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect.

213. Defendants' conducted violated the following state antitrust laws:

- a. Ala. Code § 6-5-60, with respect to purchases in Alabama by the members of the Class;
- b. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by the members of the Class;
- c. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by the members of the Class;
- d. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by the members of the Class;
- e. Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the members of the Class;
- f. 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the members of the Class;
- g. Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by the members of the Class;
- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by the members of the Class;

- i. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the members of the Class;
- j. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by the members of the Class;
- k. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by the members of the Class;
- l. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by the members of the Class;
- m. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the members of the Class;
- n. Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by the members of the Class, in that thousands of sales of branded and generic versions of Exforge® took place at Nevada pharmacies, purchased by Nevada indirect purchasers at supra-competitive prices caused by Defendant's conduct;
- o. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by the members of the Class;
- p. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by the members of the Class;
- q. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by the members of the Class;
- r. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by the members of the Class;
- s. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by the members of the Class;
- t. Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by the members of the Class;
- u. S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by the members of the Class;
- v. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by the members of the Class, with thousands of indirect purchasers in Tennessee paying substantially higher prices for branded and generic versions of Exforge® at Tennessee pharmacies;
- w. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by the members of the Class who are either citizens or residents of Utah;

- x. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by the members of the Class;
- y. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by the members of the Class; and
- z. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by the members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of indirect purchasers in Wisconsin paying substantially higher prices for branded and generic versions of Exforge® at Wisconsin pharmacies.

214. LEHB and the members of the Class have been injured in their business or property by Novartis' and Par's antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Exforge®, and (2) paying higher prices for these products than they would have paid in the absence of Novartis' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Novartis' conduct unlawful.

215. LEHB and the members of the Class seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Novartis' anticompetitive conduct.

SECOND CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law
(Against Novartis)

216. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraphs as though fully set forth herein.

217. Novartis has knowingly engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Exforge®. The intended and accomplished goal of the scheme was to use exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Exforge®. Novartis's exclusionary conduct maintained Novartis's monopoly over branded and generic Exforge®.

218. Plaintiffs and the members of the Class have suffered harm as a result of paying higher prices for Exforge® and/or its AB-rated generic equivalents than they would have absent Novartis's anticompetitive conduct and continuing anticompetitive conduct.

219. Novartis's conducted violated the following state antitrust laws:

- a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by the members of the Class;
- b. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by the members of the Class;
- c. D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;
- d. Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by the Members of the Class;
- e. 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the members of the Class;
- f. Iowa Code §§ 553, *et seq.*, with respect to purchases in Iowa by the members of the Class;
- g. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class;
- h. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by the members of the Class;
- i. Mich. Comp. Laws Ann §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the class;
- j. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;
- k. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class;
- l. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by the members of the class;
- m. Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Class, in that thousands of sales of branded and generic versions of Exforge® took place at Nevada pharmacies, purchased by Nevada indirect purchasers at supra-competitive prices caused by Defendant's conduct.

- n. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by the members of the Class;
- o. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by the members of the Class;
- p. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by the members of the Class;
- q. N.C. Gen. Stat §§ 75-1, *et seq.*, with respect to purchases in North Carolina by the members of the Class;
- r. N.D. Cent. Code §§ 51-08. 1-01, *et seq.*, with respect to the purchases in North Dakota by the members of the Class;
- s. Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by the members of the Class;
- t. S.D. Codified Laws Ann §§ 37-1, *et seq.*, with respect to purchases in South Dakota by the members of the Class;
- u. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by the members of the Class, with thousands of indirect purchasers in Tennessee paying substantially higher prices for branded and generic versions of Exforge® at Tennessee pharmacies;
- v. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class who are either citizens or residents of Utah;
- w. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;
- x. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by the members of the Class;
- y. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that actions alleged substantially affected the people of Wisconsin, and the thousands of indirect purchasers in Wisconsin paying substantially higher prices for branded and generic versions of Exforge® at Wisconsin pharmacies.

220. LEHB and the members of the class have been injured in their business or property by Novartis's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Exforge and (2) paying higher prices for these products than they would have paid in the absence of Novartis's wrongful conduct. These injuries are of the

type the above antitrust laws were designed to prevent and flow from that which makes Novartis's conduct unlawful.

221. LEHB and the members of the class seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Novartis's anticompetitive conduct.

THIRD CLAIM FOR RELIEF
Violation of State Consumer Protection Statutes
(Against All Defendants)

222. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraphs as though fully set forth herein.

223. Novartis and Par engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices by knowingly acting in restraint of trade or commerce by maintaining, at non-competitive and artificially inflated levels, the prices at which Exforge® and its AB-rated generic equivalents were sold, distributed, or obtained in the following states, and took efforts to conceal their conduct from LEHB and members of the Class. Novartis' and Par's aforementioned conduct constituted "unconscionable" and "deceptive" acts or practices in violation of the laws of the following states. Novartis' and Par's unlawful conduct had the following effects: (1) fixed combination products comprising amlodipine and valsartan price competition was restrained, suppressed, and eliminated throughout the states listed below; (2) Exforge® and its generic equivalent prices were raised, maintained, and stabilized at artificially high levels throughout the states listed below; (3) LEHB and members of the Class were deprived of free and open competition; and (4) LEHB and members of the Class paid supra-competitive, artificially inflated prices for Exforge® and its AB-rated generic equivalents. During the Class Period:

- a. Novartis and Par engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Alaska Statute § 45.50.471, *et seq.*;

- b. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Arkansas Code Annotated, § 4-88-101, *et seq.*;
- c. Novartis and Par engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;
- d. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Colorado Consumer Protection Act, Colorado Rev. Stat. § 6-1-101, *et seq.*;
- e. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Delaware Consumer Fraud Act, 6 Del. Code § 2511, *et seq.*
- f. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of District of Columbia Code § 28-3901, *et seq.*;
- g. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.*;
- h. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Georgia Uniform Deceptive Trade Practices Act, Georgia Code § 10-1-370, *et seq.*;
- i. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Hawaii Revised Statutes Annotated § 480-1, *et seq.*;
- j. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of Massachusetts Gen. Laws, Ch. 93A, § 1, *et seq.*;
- k. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Michigan Consumer Protection Statute, Mich. Compiled Laws § 445.903, *et seq.*;
- l. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.43, *et seq.*;
- m. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*;

- n. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Montana Unfair Trade Practices and Consumer Protection Act of 1970, Mont. Code, § 30-14-103, *et seq.*, and § 30-14-201, *et seq.*;
- o. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;
- p. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 598.0903, *et seq.*;
- q. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the New Hampshire Consumer Protection Act, N.H. Rev. Stat. § 358-A:1, *et seq.*;
- r. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the New Jersey Consumer Fraud Act, N.J. Statutes § 56:8-1, *et seq.*;
- s. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the New Mexico Stat. § 57-12-1, *et seq.*;
- t. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;
- u. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of North Carolina Gen. Stat. § 75-1.1, *et seq.*;
- v. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the North Dakota Unlawful Sales or Advertising Practices Statute, N.D. Century Code § 51-15-01, *et seq.*;
- w. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Pennsylvania Unfair Trade Practice and Consumer Protection Act, 73 Pa. Stat. Ann. §§ 201–1, *et seq.*;
- x. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Rhode Island Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws § 6-13.1-1, *et seq.*;
- y. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-10, *et seq.*;

- z. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the South Dakota Deceptive Trade Practices and Consumer Protection Statute, S.D. Codified Laws § 37-24-1, *et seq.*;
- aa. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Utah Consumer Sales Practices Act, Ut. Stat. § 13-11-1, *et seq.*;
- bb. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of 9 Vermont Statutes § 2451, *et seq.*;
- cc. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Virginia Consumer Protection Act of 1977, Va. Code § 59.1-196, *et seq.*;
- dd. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the West Virginia Consumer Credit and Protection Act, W.Va. Code § 46A-6-101, *et seq.*;
- ee. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the Wisconsin Consumer Protection Statutes, Wisc. Stat. § 100.18, *et seq.*; and
- ff. Novartis and Par engaged in unfair competition or unfair, unconscionable, or deceptive acts or practices in violation of the U.S. Virgin Islands Consumer Fraud and Deceptive Business Practices Act, 12A V.I.C. §§ 102, 301-35, *et seq.*

224. As a direct and proximate result of Novartis' and Par's unlawful conduct, LEHB and members of the Class have been injured and are threatened with further injury. Novartis and Par have engaged in unfair competition or unfair or deceptive acts or practices in violation of the above-referenced statutes, and, accordingly, LEHB and members of the Class seek all relief available under those statutes.

FOURTH CLAIM FOR RELIEF

Unjust Enrichment (Against All Defendants)

225. LEHB hereby repeats and incorporates by reference each preceding and succeeding paragraphs as though fully set forth herein.

226. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

227. Novartis and Par unlawfully benefited from their sales of Exforge® and its AB-rated generic equivalents because of the unlawful and inequitable acts alleged in this Complaint. Novartis and Par unlawfully overcharged LEHB, who made purchases of or reimbursements for Exforge® and its AB-rated generic equivalents at prices that were more than they would have been but for Novartis' and Par's unlawful actions.

228. Novartis' and Par's financial benefits resulting from its unlawful and inequitable acts are traceable to overpayments by LEHB and the Class. LEHB and the Class have conferred upon Novartis and Par an economic benefit, in the nature of profits resulting from unlawful overcharges, to the economic detriment of LEHB and the Class.

229. Novartis and Par have been enriched by revenue resulting from unlawful overcharges for Exforge® and its AB-rated generic equivalents while LEHB and the Class have been impoverished by the overcharges they paid for Exforge® and its AB-rated generic equivalents imposed through Novartis' and Par's unlawful conduct.

230. Novartis' and Par's enrichment and LEHB's and the Class's impoverishment are connected.

231. There is no justification for Novartis' and Par's retention of, and enrichment from, the benefits they received that caused impoverishment to LEHB and the Class, because LEHB and the Class paid supra-competitive prices that inured to Novartis' and Par's benefit, and it would be inequitable for Novartis and Par to retain any revenue gained from their unlawful overcharges.

232. LEHB and the Class did not interfere with Novartis' and Par's affairs in any manner that conferred these benefits upon Novartis or Par.

233. The benefits conferred upon Novartis and Par were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Novartis' and Par's illegal and unfair actions to inflate the prices of Exforge® and its AB-rated generic equivalents.

234. The benefits conferred upon Novartis and Par are measurable, in that the revenue Novartis and Par earned due to their unlawful overcharges for Exforge® and its AB-rated generic equivalents is ascertainable by review of sales records.

235. It would be futile for LEHB and the Class to seek a remedy from any party with whom they have privity of contract. Novartis and Par paid no consideration to any other person for any of the unlawful benefits it received indirectly from LEHB and the Class with respect to Novartis' and Par's sales of Exforge® and its AB-rated generic equivalents.

236. It would be futile for LEHB and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Exforge® and its AB-rated generic equivalents, as the intermediaries are not liable and cannot reasonably be expected to compensate LEHB and the Class for Novartis' and Par's unlawful conduct.

237. The economic benefit of overcharges and monopoly profits derived by Novartis and Par through charging supra-competitive and artificially inflated prices for Exforge® and its AB-rated generic equivalents is a direct and proximate result of Novartis' and Par's unlawful practices.

238. The financial benefits derived by Novartis and Par rightfully belong to LEHB and the Class, because LEHB and the Class paid supra-competitive prices during the Class Period, inuring to the benefit of Novartis and Par.

239. It would be inequitable under unjust enrichment principles under the laws of all States (except Ohio and Indiana) and of the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, for Novartis and Par to be permitted to retain any of the overcharges for Exforge® and its AB-rated generic equivalents derived from Novartis' and Par's unlawful, unfair, and unconscionable methods, acts, and trade practices alleged in this Complaint.

240. Novartis and Par are aware of and appreciate the benefits bestowed upon them by LEHB and the Class. Novartis and Par consciously accepted the benefits and continue to do so as of the date of this filing.

241. Novartis and Par should be compelled to disgorge in a common fund for the benefit of LEHB and the Class all unlawful or inequitable proceeds they received from their sales of Exforge® and its AB-rated generic equivalents.

242. A constructive trust should be imposed upon all unlawful or inequitable sums received by Novartis and Par traceable to indirect purchases of Exforge® and its AB-rated generic equivalents by LEHB and the Class.

243. LEHB and the Class have no adequate remedy at law.

244. By engaging in the foregoing unlawful or inequitable conduct depriving LEHB and the Class of the opportunity to purchase lower-priced Exforge® and its AB-rated generic equivalents and forcing them to pay higher prices for both, Novartis and Par have been unjustly enriched in violation of the common law of the following jurisdictions:

- a. District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the following states:
- b. State of Alabama;
- c. State of Alaska;
- d. State of Arizona;

- e. State of Arkansas;
- f. State of California;
- g. State of Colorado;
- h. State of Connecticut;
- i. State of Delaware;
- j. State of Florida;
- k. State of Georgia;
- l. State of Hawaii;
- m. State of Idaho;
- n. State of Illinois;
- o. State of Iowa;
- p. State of Kansas;
- q. Commonwealth of Kentucky;
- r. State of Louisiana;
- s. State of Maine;
- t. State of Maryland;
- u. Commonwealth of Massachusetts;
- v. State of Michigan;
- w. State of Minnesota;
- x. State of Mississippi;
- y. State of Missouri;
- z. State of Montana;
- aa. State of Nebraska;
- bb. State of Nevada;
- cc. State of New Hampshire;

dd. State of New Jersey;
ee. State of New Mexico;
ff. State of New York;
gg. State of North Carolina;
hh. State of North Dakota;
ii. State of Oklahoma;
jj. State of Oregon;
kk. Commonwealth of Pennsylvania;
ll. State of Rhode Island;
mm. State of South Carolina;
nn. State of South Dakota;
oo. State of Tennessee;
pp. State of Texas;
qq. State of Utah;
rr. State of Vermont;
ss. Commonwealth of Virginia;
tt. State of Washington;
uu. State of West Virginia;
vv. State of Wisconsin; and
ww. State of Wyoming.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully demands that this Court:

A. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of

this action, as provided by Rule 23(c)(2), be given to the Class, and declare Plaintiff as the representative of the Class;

B. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

D. Award the Class damages, and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial;

E. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

F. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XVI. JURY DEMAND

245. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: June 20, 2018

GRANT & EISENHOFER P.A.

/s/ Robert G. Eisler

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